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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/785,019	02/15/2001	Alexander Gaiger	210121.465C4	3923

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EXAMINER

SCHWADRON, RONALD B

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/785,019

Applicant(s)

GAIGER ET AL.

Examiner

Ron Schwadron, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 51-54 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,51-54 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

1. Claims 1,51-54 are under consideration.
2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.
The oath or declaration is defective because it claims priority to applications to which priority is no longer claimed.
3. Regarding the IDS filed 6/18/2001, now that the instant application is no longer claiming priority to the applications disclosed in the IDS cover letter(page 1), copies of the references cited in said IDS (except US Patents) are required.
4. The rejection of claims 48,50,52-54 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons elaborated in the previous Office Action are withdrawn in view of the cancellation of claims 48 and 50, and the amendments to claims 52-54
5. The rejection of claims 1,2,6,7,50-54 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons elaborated in paragraph 12 of the previous Office Action is withdrawn in view of the amended claims and cancellation of claims 2,6,7,50.
6. The rejection of claims 47,50-54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons elaborated in paragraph 13 of the previous Office Action is withdrawn in view of the amended claims and cancellation of claims 47,50.
7. The rejection of claims 1,2,6,7,47,48,50,51 under 35 U.S.C. 102(b) as being anticipated by Herlyn et al. (WO 95/29995) for the reasons elaborated in the previous

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Office Action is withdrawn in view of the amended claims and cancellation of claims 2,6,7,47,48,50.

8. The rejection of claims 1,2,6,7,47,50-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Sugiyama et al. (WO 00/06602) as evidenced by EP1103564 for the reasons elaborated in the previous Office Action is withdrawn in view of the amended claims and cancellation of claims 2,6,7,47,50.

9. The rejection of claims 1,2,6,7,47,48,50-54 as provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1,6,7,46-51,55,57,59-62 of copending Application No. 09/684361 for the reasons elaborated in the previous Office Action is withdrawn in view of the amended claims and cancellation of claims 2,6,7,47,48,50.

10. The rejection of claims 1,2,6,7,47,50-54 as provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 104,107-112 of copending Application No. 09/16423 for the reasons elaborated in the previous Office Action is withdrawn in view of the amended claims and cancellation of claims 2,6,7,47,48,50.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1,51-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaiger et al. (2000) in view of Xu et al. (US Patent 6,818,751).

SEQ. ID. No 335 recited in claim 1 contains a N terminal his tag attached to the partial WT1 sequence recited in said claim.

Gaiger et al. discloses a his tag fusion protein containing the WT1 N terminal protein sequence recited in claim 1 (see page 1482, section "Recombinant protein purification"). The intact WT1 sequence was already known in the prior art (see page 1480, second column, last paragraph). The fusion protein disclosed by Gaiger et al. differs from the claimed peptide in that it has two his tags and other amino acids not recited in claim 1. Xu et al. disclose a fusion protein wherein said protein has the same his tag as contained in SEQ. ID. No 335 (see column 114, second paragraph, wherein the his tag on SEQ. ID. No. 842 is the same as that contained in SEQ. ID. No 335 recited in claim 1). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Gaiger teach the claimed polypeptide except for the particular his tag used and the particular his tag used was known in the art as per Xu et al. One of ordinary skill in the art would have been motivated to do the aforementioned as an alternative method for producing a WT1/histag fusion protein. Xu et al. discloses compositions containing tumor cell antigens and a microsphere (see column 68). Xu et al. discloses compositions containing tumor cell antigens and a nonspecific immune enhancer which enhances a T cell response (AKA cell mediated response)(see column 68, second paragraph and column 70).). Xu et al. discloses compositions containing tumor cell antigens and a excipient (see column 69, last paragraph). The WT1 sequence recited in the claims encodes a tumor cellular antigen.

13. No claim is allowed.


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14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached Monday to Thursday from 730am to 6:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571 272 0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644



RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1800 lbr